NOV 1 3 2000

K002552

510(k) Summary

Device: Howmedica Osteonics Modular Rotating Hinge Knee – Additional Indications

The Howmedica Osteonics Modular Rotating Hinge Knee Components (K994207, K001548, and K001957) are presently cleared for use with bone cement in cases where there is destruction of the joint surfaces, with or without significant bone deformity; the cruciate and/or collateral ligaments do not stabilize the knee joint; the ligaments are inadequate and/or the musculature is weak; and revision is required of a failed prostheses where there has been gross instability, with or without bone loss or inadequate soft tissue.

Howmedica Osteonics seeks clearance to expand these indications to include the devices referenced in the aforementioned 510(k) submissions for use with bone cement in oncology patients where radical resection and replacement of either the distal femur or proximal tibia is required. Additionally, this device would be intended for use with bone cement in limb salvage procedures where radical resection and replacement of the distal femur/ proximal tibia is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous knee arthroplasties, infection, and/or Oncology indications. All of these surgical interventions have in common the need for radical resection of the distal femur/ proximal tibia, and the need for a prosthetic replacement.

Lastly, the Modular Rotating Hinge Knee components are intended to be mated with corresponding components of the Howmedica® Modular Replacement (MRS) System (K952970, K972401) and the Kinematic™ Rotating Hinge Knee (KRH) System (K792089).

This submission also includes a Reverse Crossover Tibial Bearing Component which will mate the Kinematic™ Rotating Hinge Knee (KRH) and Modular Replacement System (MRS) femoral components, (including the bushings, axles and bumpers), with the Modular Rotating Hinge Knee tibial components thus offering the surgeon a wider range of tibial and femoral component sizing options.

The Modular Rotating Hinge Knee Components are substantially equivalent the Howmedica® Modular Replacement System Distal Femur/ Proximal Tibial Segments Additional Indications – Howmedica Osteonics (K972401), the Kinematic™ Rotating Hinge Knee System – Howmedica Osteonics (K792089), and the Modular Rotating Hinge Knee Crossover Tibial Bearing Components – Howmedica Osteonics (K001548, K001957)

For information contact: Jennifer A. Daudelin
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2000

Ms. Jennifer Daudelin
Regulatory Affairs
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K002552
Trade Name: Howmedica Osteonics Modular Rotating Hinge Knee
Regulatory Class: II
Product Code: KRO
Dated: August 16, 2000
Received: August 17, 2000

Dear Ms. Daudelin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K002552

Device Name: Howmedica Osteonics Modular Rotating Hinge Knee – Additional Indications

Indications for Use:

The Howmedica Osteonics Modular Rotating Hinge Knee Components is intended for use with bone cement in cases where there is destruction of the joint surfaces, with or without significant bone deformity; the cruciate and/or collateral ligaments do not stabilize the knee joint; the ligaments are inadequate and/or the musculature is weak; and revision is required of a failed prostheses where there has been gross instability, with or without bone loss or inadequate soft tissue.

In addition, expanded indications include for use with bone cement in oncology patients where radical resection and replacement of either the distal femur or proximal tibia is required. Additionally, this device would be intended for use with bone cement in limb salvage procedures where radical resection and replacement of the distal femur/ proximal tibia is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous knee arthroplasties, infection, and/or Oncology indications. All of these surgical interventions have in common the need for radical resection of the distal femur/ proximal tibia, and the need for a prosthetic replacement.

The Modular Rotating Hinge Knee components are intended to be mated with corresponding components of the Howmedica® Modular Replacement (MRS) System (K952970, K972401) and the Kinematic™ Rotating Hinge Knee (KRH) System (K792089).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

for Mark N Milham (Optional Format 1-2-96)
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002552